



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,847	11/23/2005	Charles Henry Horn	05-037	1275
20306 7590 06/29/2007 MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606			EXAMINER ARIANI, KADE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 06/29/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,847	<b>Applicant(s)</b> HORN ET AL.	
	<b>Examiner</b> Kade Ariani	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

***DETAILED ACTION***

The preliminary amendment filed on November 23, 2005, has been received and entered.

Claims 1-22 have been canceled.

Claims 23-47 are pending in this application and were examined on their merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 26, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "substantially the same 16S ribosomal RNA sequence" in claim 23 and is indefinite because it is unclear what percentage of the 16S ribosomal RNA sequence must be homologous for the bacterial strain to be considered substantially the same sequence. Also the recitation "further characterized by its ability to utilize lactate efficiently.... and relatively high growth rate..." in claim 26 is indefinite since it is not clear what is being claimed by the applicant.

The recitation "superior" and "inferior" rumen microorganism in claim 40 is also indefinite, because, these adjectives are relative terms and thus it is not clear what is being claimed.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23-39 are rejected under 35 U.S.C. 101, because the claimed invention is directed to non-statutory subject matter.

Claims 23-27 are directed to "*M. elsdenii*" bacterial cells and their qualities. *M. elsdenii* cells are naturally occurring ruminal bacteria and are not a "manufacture". The claims do not require any physical transformation of the bacterial cells. The claimed invention would impermissibly cover every substantial practical application of, and thereby preempt all use of a product of nature.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23 and 40-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Leedle et al. (US Patent No. 5,380,525, issued Jan. 10, 1995).

Claim 23 is drawn to a bacterial culture of *M. elsdenii*.

Leedle et al. discloses a bacterial culture of *M. elsdenii* (see claim 1). In general organisms sharing more than 97% ribosomal RNA similarity may belong to a single species and since the bacterial culture disclosed by Leedle et al. belongs to a *M. elsdenii* species therefore, it must have substantially the same 16S ribosomal RNA (rRNA) sequence with the claimed bacterial strain and the same lactate-degrading abilities which are important in controlling acidosis by removing lactic acid through catabolic action.

Claims 40-47 are drawn to a method of isolating a culture of a ruminal microorganism comprising obtaining a sample of ruminal fluids and cultivating the sample on a growth medium, a composition comprising a bacterial culture of *M. elsdenii*, a method comprising administering an effective amount of that composition, and ruminal lactic acidosis.

Leedle et al. further discloses a method of isolating and a culture of a ruminal microorganism comprising obtaining a sample of ruminal fluids and cultivating the sample on a growth medium, a method of preventing acute lactic acidosis comprising administering an effective amount of a bacterial culture of *M. elsdenii* (see abstract, claims 1-4, columns 2 and 3, Example 1).

Leedle et al. therefore clearly anticipated the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23- 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leedle et al. (US Patent No. 5,380,525, issued Jan. 10, 1995).

Claims 23-47 are drawn to a composition comprising a bacterial culture of *M. elsdenii* strain 41125, a method comprising administering to the rumen of ruminants an effective amount of the composition, and ruminal lactic acidosis.

As mentioned immediately above Leedle et al. teaches the limitations of claims 23 and 40-47. Leedle et al. does not teach strain 41125. However, at the time the invention was made it was very well known in the art that different strains of *M. elsdenii* were able to prevent lactate accumulation and excessive drop in pH in ruminal fermentation.

Therefore, in view of the above teachings, at the time the invention was made it would have been obvious to one of the ordinary skill in the art to provide a composition comprising a bacterial culture of *M. elsdenii* and administering an effective amount of that composition to the rumen of a ruminant for the treatment of ruminal lactic acidosis. One would have been motivated to provide a composition comprising a bacterial culture of *M. elsdenii* and administering an effective amount of that composition to the rumen of a ruminant for the treatment of ruminal lactic acidosis with a reasonable expectation of

Art Unit: 1651

success, because at the time the invention was made lactate-degrading abilities of several strains of *M. elsdenii* were very well known in the art, also, several strains of *M. elsdenii* were being used for the same purpose.

Accordingly, the invention taken as whole is *prima facie* obvious in view of the prior art.

### ***Conclusion***

No claims are allowed.

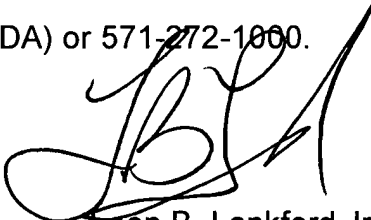
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani  
Examiner  
Art Unit 1651



Leon B. Lankford Jr.  
Primary Examiner  
Art Unit 1651